January 22, 2016

SENATE BILL No. 187

DIGEST OF SB 187 (Updated January 20, 2016 12:51 pm - DI 104)

Citations Affected: IC 16-18; IC 16-19; IC 16-31; IC 16-42; IC 25-26.

Synopsis: Overdose intervention drugs reporting and standing orders. Requires the state department of health to ensure that a statewide standing order for the dispensing of an overdose intervention drug is issued for Indiana. Allows the state health commissioner or a public health authority to issue a statewide standing order for the dispensing of an overdose intervention drug. Requires a pharmacy to keep records for two years of the dispensing of an overdose intervention drug through a standing order. Requires certain emergency ambulance service responsible for submitting the report the number of times an overdose intervention drug has been administered. Requires the ambulance service to include the information in the emergency ambulance service's report to the emergency medical services commission under the emergency medical services system review.

Effective: July 1, 2016.

Merritt, Miller Patricia, Charbonneau, Crider, Mrvan

January 6, 2016, read first time and referred to Committee on Health & Provider Services.
January 21, 2016, amended, reported favorably — Do Pass.

January 22, 2016

Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

SENATE BILL No. 187

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-18-2-298.5, AS ADDED BY P.L.138-2006, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 298.5. **(a)** "Public health authority", for purposes of IC 16-22-8, and IC 16-41-9, means:

(1) the state health commissioner of the state department;

(2) a deputy or an assistant state health commissioner appointed by the state health commissioner, or an agent expressly authorized by the state health commissioner;

(3) the local health officer; or

(4) a health and hospital corporation established under IC 16-22-8-6.

(b) "Public health authority", for purposes of IC 16-42-27, means any of the following who is a licensed prescriber:

(1) A deputy or assistant state health commissioner appointed by the state health commissioner to act as a public health authority.

(2) An agent employed by the state department that is

expressly authorized by the state health commissioner to act as a public health authority.

SECTION 2. IC 16-19-4-4, AS AMENDED BY P.L.126-2012, SECTION 36, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 4. (a) The state health commissioner is governed in the performance of the state health commissioner's official duties by IC 4-2-6 and IC 35-44.1-1-4 concerning ethics and conflict of interest.

(b) To learn professional skills and to become familiar with new developments in the field of medicine, **and except as provided in IC 16-42-27-2(f),** the state health commissioner may, in an individual capacity as a licensed physician and not in an official capacity as state health commissioner, engage in the practice of medicine if the practice of medicine does not interfere with the performance of the state health commissioner's duties as state health commissioner.

SECTION 3. IC 16-19-4-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 5. **This section does not apply to the prescribing, dispensing, or issuance of a standing order for an overdose intervention drug under IC 16-42-27-2.** Any medical care provided to a patient by the state health commissioner is provided by the state health commissioner in an individual capacity as a licensed physician and the state is not liable for any act performed by the state health commissioner in this capacity.

SECTION 4. IC 16-31-3-23.7, AS ADDED BY P.L.32-2015, SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 23.7. **(a)** An advanced emergency medical technician, an emergency medical responder, an emergency medical technician, a firefighter, a volunteer firefighter, a law enforcement officer, or a paramedic who:

(1) administers an overdose intervention drug; or

(2) is summoned immediately after ~~administering the~~ **an** overdose intervention drug **is administered;**

shall ~~report~~ **inform the emergency ambulance service responsible for submitting the report to the commission of** the number of times an overdose intervention drug ~~is dispensed to the state department under the state trauma registry in compliance with rules adopted by the state department.~~ **has been administered.**

(b) The emergency ambulance service shall include information received under subsection (a) in the emergency ambulance service's report to the commission under the emergency medical services system review in accordance with the commission's rules.

SECTION 5. IC 16-42-27-1, AS ADDED BY P.L.32-2015, SECTION 7, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE

JULY 1, 2016]: Sec. 1. As used in this chapter, "prescriber" means any of the following:

(1) A physician licensed under IC 25-22.5.

(2) A physician assistant licensed under IC 25-27.5 and granted the authority to prescribe by the physician assistant's supervisory physician and in accordance with IC 25-27.5-5-4.

(3) An advanced practice nurse licensed and granted the authority to prescribe drugs under IC 25-23.

(4) The state health commissioner, if the state health commissioner holds an active license under IC 25-22.5.

(5) A public health authority.

SECTION 6. IC 16-42-27-2, AS ADDED BY P.L.32-2015, SECTION 7, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 2. (a) A prescriber may, directly or by standing order, prescribe or dispense an overdose intervention drug without examining the individual to whom it may be administered if all of the following conditions are met:

(1) The overdose intervention drug is dispensed or prescribed to:

(A) a person at risk of experiencing an opioid-related overdose; or

(B) a family member, a friend, or any other individual or entity in a position to assist an individual who, there is reason to believe, is at risk of experiencing an opioid-related overdose.

(2) The prescriber instructs the individual receiving the overdose intervention drug or prescription to summon emergency services either immediately before or immediately after administering the overdose intervention drug to an individual experiencing an opioid-related overdose.

(3) The prescriber provides education and training on drug overdose response and treatment, including the administration of an overdose intervention drug.

(4) The prescriber provides drug addiction treatment information and referrals to drug treatment programs, including programs in the local area and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, nonaddictive medication for the treatment of opioid or alcohol dependence.

(b) A prescriber may provide a prescription of an overdose intervention drug to an individual as a part of the individual's addiction treatment plan.

(c) An individual described in subsection (a)(1) may administer an overdose intervention drug to an individual who is suffering from an

overdose.

(d) An individual described in subsection (a)(1) may not be considered to be practicing medicine without a license in violation of IC 25-22.5-8-2, if the individual, acting in good faith, does the following:

(1) Obtains the overdose intervention drug from a prescriber **or entity acting under a standing order issued by a prescriber.**

(2) Administers the overdose intervention drug to an individual who is experiencing an apparent opioid-related overdose.

(3) Attempts to summon emergency services either immediately before or immediately after administering the overdose intervention drug.

(e) An entity acting under a standing order issued by a prescriber must do the following:

(1) Annually register with either the:

(A) state department; or

(B) local health department in the county where services will be provided by the entity;

in a manner prescribed by the state department.

(2) Provide education and training on drug overdose response and treatment, including the administration of an overdose intervention drug.

(3) Provide drug addiction treatment information and referrals to drug treatment programs, including programs in the local area and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, nonaddictive medication for the treatment of opioid or alcohol dependence.

(f) The state department shall ensure that a statewide standing order for the dispensing of an overdose intervention drug in Indiana is issued under this section. The state health commissioner or a designated public health authority who is a licensed prescriber may, as part of the individual's official capacity, issue a statewide standing order that may be used for the dispensing of an overdose intervention drug under this section. The immunity provided in IC 34-13-3-3 applies to an individual described in this subsection.

SECTION 7. IC 25-26-13-25, AS AMENDED BY P.L.13-2013, SECTION 69, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A

prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. **A pharmacy shall keep a record for at least two (2) years of the dispensing of an overdose intervention drug (as defined in IC 16-18-2-263.9) through the use of a standing order under IC 16-42-27-2.** The files shall be open for inspection to any member of the board or the board's duly authorized agent or representative.

(b) A prescription may be electronically transmitted from the practitioner by computer or another electronic device to a pharmacy that is licensed under this article or any other state or territory. An electronic data intermediary that is approved by the board:

(1) may transmit the prescription information between the prescribing practitioner and the pharmacy;

(2) may archive copies of the electronic information related to the transmissions as necessary for auditing and security purposes; and

(3) must maintain patient privacy and confidentiality of all archived information as required by applicable state and federal laws.

(c) Except as provided in subsection (d), a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written, electronically transmitted, or oral authorization of a licensed practitioner.

(d) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written, electronically transmitted, or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (h).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a

refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (e).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

(e) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(f) The original prescription form or the other board approved record described in subsection (e) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(g) This subsection does not apply:

(1) unless a patient requests a prescription drug supply of more than thirty (30) days;

(2) to the dispensing of a controlled substance (as defined in IC 35-48-1-9); or

(3) if a prescriber indicates on the prescription that the quantity of the prescription may not be changed.

A pharmacist may dispense, upon request of the patient, personal or legal representative of the patient, or guardian of the patient, not more than a ninety (90) day supply of medication if the patient has completed an initial thirty (30) day supply of the drug therapy and the prescription, including any refills, allows a pharmacist to dispense at least a ninety (90) day supply of the medication. However, a pharmacist shall notify the prescriber of the change in the quantity filled and must comply with state and federal laws and regulations concerning the dispensing limitations concerning a prescription drug. The pharmacist shall inform the customer concerning whether the additional supply of the prescription will be covered under the patient's insurance, if applicable.

(h) A prescription is valid for not more than one (1) year after the original date of issue.

(i) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(j) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(k) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to an individual:

(A) residing in an institutional facility (as defined in 856 IAC 1-28.1-1(6));

(B) in a hospice program under IC 16-25; or

(C) in a county jail or department of correction facility;

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Category II permit (as described in section 17 of this chapter).

(l) A pharmacist or a pharmacy shall not resell, reuse, or redistribute medical devices or medical supplies used for prescription drug therapy that have been returned to the pharmacy after being dispensed unless the medical devices or medical supplies:

(1) were dispensed to an individual in a county jail or department of correction facility;

(2) are not expired; and

(3) are returned unopened and in the original sealed packaging.

(m) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under this section.

(n) A pharmacist who violates subsection (d) commits a Class A infraction.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 187, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 2, delete lines 23 through 35, begin a new paragraph and insert:

"SECTION 4. IC 16-31-3-23.7, AS ADDED BY P.L.32-2015, SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 23.7. **(a)** An advanced emergency medical technician, an emergency medical responder, an emergency medical technician, a firefighter, a volunteer firefighter, a law enforcement officer, or a paramedic who:

(1) administers an overdose intervention drug; or

(2) is summoned immediately after ~~administering the~~ **an** overdose intervention drug **is administered;**

shall ~~report~~ **inform the emergency ambulance service responsible for submitting the report to the commission of** the number of times an overdose intervention drug ~~is dispensed to the state department under the state trauma registry in compliance with rules adopted by the state department.~~ **has been administered.**

(b) The emergency ambulance service shall include information received under subsection (a) in the emergency ambulance service's report to the commission under the emergency medical services system review in accordance with the commission's rules.".

Page 4, after line 31, begin a new paragraph and insert:

"SECTION 7. IC 25-26-13-25, AS AMENDED BY P.L.13-2013, SECTION 69, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. **A pharmacy shall keep a record for at least two (2) years of the dispensing of an overdose intervention drug (as defined in IC 16-18-2-263.9) through the use of a standing order under IC 16-42-27-2.** The files shall be open for inspection to any member of the board or the board's duly authorized agent or representative.

(b) A prescription may be electronically transmitted from the practitioner by computer or another electronic device to a pharmacy that is licensed under this article or any other state or territory. An electronic data intermediary that is approved by the board:

(1) may transmit the prescription information between the prescribing practitioner and the pharmacy;

(2) may archive copies of the electronic information related to the transmissions as necessary for auditing and security purposes; and

(3) must maintain patient privacy and confidentiality of all archived information as required by applicable state and federal laws.

(c) Except as provided in subsection (d), a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written, electronically transmitted, or oral authorization of a licensed practitioner.

(d) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written, electronically transmitted, or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (h).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (e).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

(e) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(f) The original prescription form or the other board approved record described in subsection (e) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(g) This subsection does not apply:

(1) unless a patient requests a prescription drug supply of more than thirty (30) days;

(2) to the dispensing of a controlled substance (as defined in IC 35-48-1-9); or

(3) if a prescriber indicates on the prescription that the quantity of the prescription may not be changed.

A pharmacist may dispense, upon request of the patient, personal or legal representative of the patient, or guardian of the patient, not more than a ninety (90) day supply of medication if the patient has completed an initial thirty (30) day supply of the drug therapy and the prescription, including any refills, allows a pharmacist to dispense at least a ninety (90) day supply of the medication. However, a pharmacist shall notify the prescriber of the change in the quantity filled and must comply with state and federal laws and regulations concerning the dispensing limitations concerning a prescription drug. The pharmacist shall inform the customer concerning whether the additional supply of the prescription will be covered under the patient's insurance, if applicable.

(h) A prescription is valid for not more than one (1) year after the original date of issue.

(i) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(j) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(k) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to an individual:

(A) residing in an institutional facility (as defined in 856 IAC 1-28.1-1(6));

(B) in a hospice program under IC 16-25; or

(C) in a county jail or department of correction facility;

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Category II permit (as described in section 17 of this chapter).

(l) A pharmacist or a pharmacy shall not resell, reuse, or redistribute medical devices or medical supplies used for prescription drug therapy that have been returned to the pharmacy after being dispensed unless the medical devices or medical supplies:

(1) were dispensed to an individual in a county jail or department of correction facility;

(2) are not expired; and

(3) are returned unopened and in the original sealed packaging.

(m) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under this section.

(n) A pharmacist who violates subsection (d) commits a Class A infraction.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 187 as introduced.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 11, Nays 0.